



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2019-D-3764]**

#### **Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media; Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry (GFI) #171 entitled “Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media.” This draft guidance describes how the Agency intends to evaluate requests for waiving the requirement for performing in vivo bioequivalence studies for animal drugs administered orally as soluble powders or as Type A medicated articles manufactured from active pharmaceutical ingredients considered to be soluble in aqueous media.

**DATES:** Submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2019-D-3764 for “Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015,

or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

- Biopharmaceutics and Pharmacokinetics: Marilyn Martinez, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0635, [Marilyn.Martinez@fda.hhs.gov](mailto:Marilyn.Martinez@fda.hhs.gov).
- Manufacturing Chemistry/Solubility Concerns: Catherine Finnegan, Center for Veterinary Medicine (HFV-147), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0650, [Catherine.Finnegan@fda.hhs.gov](mailto:Catherine.Finnegan@fda.hhs.gov).
- Generic Drug Approval Requirements: Ian S. Hendricks, Center for Veterinary Medicine (HFV-172), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0853, [Ian.Hendricks@fda.hhs.gov](mailto:Ian.Hendricks@fda.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

FDA is announcing the availability of a draft GFI #171 entitled “Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media.” This draft guidance describes how the Agency intends to evaluate requests for waiving the requirement for performing in vivo bioequivalence studies (biowaivers) for animal drugs administered orally as soluble powders or as Type A medicated articles manufactured from active pharmaceutical ingredients (APIs) considered to be soluble in aqueous media (water soluble APIs). This draft guidance expands upon GFI #35, “Bioequivalence Guidance,” published November 8, 2006, to include biowaivers for soluble powder oral dosage form products as well as Type A medicated articles manufactured from active pharmaceutical ingredients considered to be soluble in aqueous media. This draft guidance offers particular focus on criteria for the waiver of the requirements for submitting in vivo bioequivalence study data.

This draft guidance is applicable to generic investigational new animal drug (JINAD) files and to abbreviated new animal drug applications (ANADAs). Although the recommendations in this guidance refer to generic drug applications, the general principles described may also be applicable to new animal drug applications (NADAs), investigational new animal drug (INAD) files, and supplemental NADAs. This draft guidance does not address Type A medicated articles manufactured from active pharmaceutical ingredients considered to be insoluble in aqueous media.

## II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## III. Paperwork Reduction Act of 1995

This draft guidance refers to collections of information associated with biowaiver requests for generic soluble powder oral dosage form products and Type A medicated articles. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information associated with biowaiver requests for generic soluble powder oral dosage form products and Type A medicated articles are being reviewed by OMB under OMB control number 0910-0669 (see 84 FR 16270 at 16271, April 18, 2019).

## IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: September 25, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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